

1

BIOPSY DEVICE WITH APERTURE ORIENTATION AND IMPROVED TIP

FIELD OF THE INVENTION

Thee present invention relates generally to tissue removing devices such as biopsy devices and the methods of using such devices. More specifically, it is directed to an improved device and method for accessing and removing pathologically suspect tissue from within a patient's body.

BACKGROUND OF THE INVENTION

In diagnosing and treating certain medical conditions, such as potentially cancerous tumors, it is usually desirable to perform a biopsy, in which a specimen of the suspicious tissue is removed for pathological examination and analysis. In many instances, the suspicious tissue is located in a subcutaneous site, such as inside a human breast. To minimize surgical intrusion into the patient's body, it is desirable to be able to insert a small instrument into the patient's body to access the targeted site and to extract the biopsy specimen therefrom.

Electrosurgical techniques have been used in a variety of biopsy procedures. In electrosurgery, high frequency electrical energy is typically applied to patient tissue through an active electrode, the electrical circuit being completed by a return electrode in contact with the patient's tissue. Electrical energy flowing through the tissue from the active electrode is effective to ablate tissue near the active electrode, forming an opening in the tissue and so allowing insertion of the instrument into a patient's body. A return electrode may be placed on the exterior of the patient's body or may be incorporated into the device itself. The return electrode is typically attached to the patient at a point remote from where the primary or active electrode contacts the tissue. However, in the case of a bipolar electrode for example, the return electrode may be disposed near to the active electrode. An electrosurgical biopsy instrument is disclosed and claimed in U.S. patent application Ser. No. 09/159,467 for "Electrosurgical Biopsy Device and Method," now U.S. Pat. No. 6,261,241, assigned to the assignee of the present application, and which is hereby incorporated by reference in its entirety. A variety of needle like tip designs have been developed to aid in the accessing of intracorporeal sites for biopsy and other procedures. Electrosurgical techniques have also been used in a variety of biopsy procedures to gain access to an intracorporeal site. See for example U.S. Pat. No. 6,261,241, assigned to the assignee of the present application, and which is hereby incorporated by reference in its entirety.

The prior needle like tips do not always allow proper placement of the biopsy or other surgical device. Moreover, while the electrosurgical biopsy devices have been found to be effective in many instances, they are not suitable for use in conjunction with magnetic resonance imaging.

While these electrosurgical biopsy devices have been found to be effective in many instances, they may not always be suitable for use in conjunction with magnetic resonance imaging.

SUMMARY OF THE INVENTION

This invention is directed to devices for accessing and severing tissue from a target site within a patient and methods for utilizing such devices. The devices embodying features of the invention provide access to a targeted tissue site within a

2

patient and provide for the selection, separation and capture of a tissue specimen from supporting tissue at the targeted site.

A tissue accessing and severing device and system having features of the invention generally include an elongated, preferably disposable probe component having a plurality of operative elements and a driver component configured to receive the elongated probe component and drive the various operative elements of the probe component.

The elongated probe component has a distal shaft portion with a tissue penetrating distal tip, a tubular section proximal to the distal tip, an inner lumen extending within the tubular section and an open, tissue receiving aperture in the tubular section which provides access to tissue at the targeted site. The probe component includes an elongated tissue-cutting member, which is preferably at least in part cylindrically shaped. The tissue cutting member is provided with at least one tissue cutting edge which is configured to sever tissue extending into the interior of the tubular section through the aperture thereof. The cutting edge on the tissue cutting member may be configured for longitudinal cutting movement and may include oscillating rotational motion and/or reciprocating longitudinal motion to sever specimen tissue extending through the aperture from supporting tissue at the targeted site. The cutting surfaces or edges are radially spaced from a longitudinal axis of the probe component and are generally transversely oriented with respect to the longitudinal axis. The tissue cutter is preferably slidably disposed within the inner lumen of the tubular section, although it may be disposed about the tubular section. The probe component may also have a handle which releasably engages the driver component.

In one embodiment of the invention, the cutting member has an inner lumen preferably extending to the proximal end thereof for tissue specimen removal. While mechanical withdrawal of the tissue specimen may be employed, it is preferred to provide a vacuum within the cutting member from the proximal end of the cutting member. The proximal end of the cutting member may be configured to be in fluid communication with a vacuum source to aspirate the severed tissue specimen through the inner lumen of the cutting member to a tissue collection station. A higher fluid pressure may be maintained in the inner lumen of the cutting member distal to the tissue specimen to aid in transporting the specimen proximally through the inner lumen. In this manner, the mechanical withdrawal and/or the vacuum on the proximal end of the specimen and a higher pressure on the distal end of the specimen can move the specimen through the inner lumen of the cutting member to a tissue collection station.

In at least one embodiment, the handle of the probe component is secured, preferably releasably secured, to the driver housing provided to operably connect the various operative elements of the probe with operative elements of the driver component. The tissue cutting member is operatively connected to at least one driver to provide the desired cutting motion. The proximal end of the tubular section is rotatably secured within the handle housing so that the orientation thereof with respect to the longitudinal axis and therefore the orientation of the tissue receiving aperture within the tubular section, can be selected. The orientation of the aperture may be selected manually such as described in copending application Ser. No. 10/642,406, filed Aug. 15, 2003 or it may be preset or selected electronically by a control module which also controls the operation of the cutting member and electrical power. The aperture orientation setting may be selected before or after the distal portion of the probe component is inserted into the patient.